

FILED

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

UNITED STATES OF AMERICA ex rel.
M. SHAWN LAWLER, DDS

Plaintiffs,

v.

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US DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
ORLANDO, FLORIDA
1430 MHS
Case No. 6:19-cv-896-ORL-37GJL
FILED UNDER SEAL
PURSUANT TO 31 U.S.C.
§ 3730(b)(2)
DO NOT PUT IN PRESS
BOX OR INTO PACER SYSTEM

COMPREHENSIVE HEALTH SERVICES,
INC.; COMPREHENSIVE HEALTH
SERVICES, LLC; COMPREHENSIVE HEALTH
SERVICES INTERNATIONAL, LLC; CHS
MIDDLE EAST, LLC; CALIBURN INTERNATIONAL
CORPORATION; SALLYPORT GLOBAL SERVICES LTD.,

Defendants

**RELATOR MICHAEL SHAWN LAWLER, DDS's COMPLAINT PURSUANT
TO 31 U.S.C. § 3729, *et seq.* OF THE FEDERAL FALSE CLAIMS ACT**

The United States of America, by and through *qui tam* relator Michael Shawn Lawler, DDS and his counsel, bring this action under 31 U.S.C. § 3729 *et seq.*, as amended, to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States for violations by the Defendants (*see*, Part II) for knowingly and falsely obtaining and retaining the payment of false claims by the United States in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended by the Fraud Enforcement and Recovery Act of 2009 (“FERA”), 123 Stat. 1617, *et seq.*.

I. PRELIMINARY STATEMENT

1. “The United States cannot afford to have sensitive government information or systems inadequately secured by contractors. Federal contractors provide important services to the United States Government and must properly secure the systems through which they provide those services.”¹

2. To enrich themselves at the expense of the affected government agencies, Defendants(s) engaged in a scheme where they contracted to provide “a full range of clinical services, including on-site emergency care, dental, pharmaceutical, laboratory, x-ray services, resuscitative and general surgery”² in accordance with detailed, mandatory, federally-authorized and ongoing procurement requirements covering privacy and security safeguards, procurement of controlled substances and/or rendering of clinical services. Defendants knowingly supplied unauthorized, inadequate – and in some cases non-existent – safeguards and/or clinical services.

3. Given how material compliance with the Federal Acquisition Regulations (“FAR”) and the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”)³ was from the January 2011 pre-solicitation process through the award and performance of the Comprehensive Health Services (“CHS”) contract with the U.S. Department of State, and the April 2014 Sallyport Global Services, Ltd.’s subcontract with CHS Middle East, LLC to provide medical services at the Balad

¹ Office of the President of the United States, *National Cyber Strategy of the United States of America*, p. 7 (Sept. 2018), <https://www.whitehouse.gov/wp-content/uploads/2018/09/National-Cyber-Strategy.pdf>.

² See *CHS Middle East wins second major medical services contract in Iraq* (Apr. 28, 2014), <https://www.chsmedical.com/newsroom/chs-middle-east-wins-second-major-medical-services-contract-iraq>.

³ CHS Middle East, LLC and its sister companies utilized the cloud-based electronic health record Practice Partners (“EHR” or “Practice Partners”).

Air Base under the U.S. Foreign Military Sales Program, the United States would neither have contracted with the Defendants nor paid Defendants' exorbitant fees but for Defendants' false presentations, including Defendants' assessments, certifications, representations and attestations that Defendants complied with the applicable regulations described herein as a government services provider.⁴

4. This is an action to recover damages and civil penalties on behalf of the United States of America for violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 arising from false or fraudulent records, statements, or claims, or any combination thereof, made, used or caused to be made, used, or presented, or any combination thereof, by the Defendants, together with their current and former shareholders; direct and indirect subsidiaries; brother or sister corporations; divisions; current or former corporate owners; and the corporate successors and assigns of any of them, their agents, employees, or co-conspirators, or any combination thereof, with respect to the Defendants' knowing submission of false claims, and knowing retention of payment from the intentional false claims, which were submitted to the United States Government. Defendants' illegal and unlawful conduct preceded Relator's employment and continues to this day.

5. The FCA provides liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"; and who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. §§ 3729(a)(1)(A)-(B). Liability also arises for "reverse false claims," where any person "knowingly" concealed or "knowingly" and improperly avoided or decreased an

⁴ Arleen Thukral, MS, CCE, CHTM, *What the Cloud Can Do for Healthcare* (Jul. 26, 2018) (indicating that FedRAMP compliance, ongoing audits and other safeguards are material to contracting with the United States Government), <http://www.24x7mag.com/2018/07/cloud-can-healthcare/>.

obligation to reimburse the United States. 31 U.S.C. § 3729(a)(1)(G).

6. It is unknown if any comprehensive audits were conducted both in the United States and abroad in locations such as the Balad Air Base. In May 2017, Kirkpatrick Price was hired by Defendant CHS to perform a Type II SOC 2 Audit.⁵

7. In addition to FAR and HIPAA, requisite National Institute of Standards and Technology (“NIST”) standards are set out in NIST Special Publications which “provides a catalog of security and privacy controls for federal information systems and organizations and a process for selecting controls to protect organizational operations.”⁶

8. In addition to FAR, HIPAA and NIST compliance, government agencies may also require Service Level Agreements (“SLA”), Data Use Agreements (“DUA”) and/or Business Associate Agreements (“BAA”) with a government contractor. If the agency is listed as “using this service,” contracts and/or purchase agreements are also executed.

9. Dr. Lawler acquired first-hand knowledge about the 2011 procurement process which resulted in a contract (SAQMMA 11-R-0010) with the U.S. Department of State to provide medical services in Iraq that were “in accordance with US or equivalent [European Union] medical standards on a 24 hour basis, 365 days of the year”⁷ and the 2014 Sallyport Global Services Ltd. contract, which subcontracted to CHS Middle East LLC to provide medical services at Balad Air

⁵ CHS, *Comprehensive Health Services Completes SOC II Audit in November* (Dec. 4, 2017), <https://www.chsmedical.com/newsroom/comprehensive-health-services-completes-soc-ii-audit-november>.

⁶ National Institute of Standards and Technology, *SP 800-53, Rev. 4* (Apr. 2013), available at: <https://csrc.nist.gov/publications/detail/sp/800-53/rev-4/final>.

⁷ Pre-solicitation Materials are attached as **Exhibit 1**.

Base (Contract No. FA861514C6020).⁸ Dr. Lawler observed the initial and continued lack of compliance with the privacy and security requirements under the HIPAA Security Rule, Privacy Rule, and NIST 800-53, rev. 4, as well as lack of compliance with the pharmacy operations including dispensing of drugs by pharmacy techs when no pharmacists was present and the purchase of controlled substances (i.e., tramadol hydrochloride) from non-United States or non-European Union manufacturers. Instead, Defendants opted to use Austell Laboratories (Pty) Ltd., 52 Mineral Crescent, Crown Ext. 3, Johannesburg, 2092, South Africa⁹ and charged the United States Government far in excess of what the Defendants' cost was to procure the drugs illegally.

10. Relator seeks to recover on behalf of the United States treble damages and civil penalties arising from Defendants' making or causing to be made false or fraudulent records, statements and/or claims in connection with its procurement and contracting with various government agencies to provide clinical services which rely on NIST standards and a cloud-based HER. Had it been aware of Defendants' false certifications of compliance, fraudulent practices, and scheme to increase profits through supplying non-compliant, inadequate or non-existent services, which places the privacy and security of United States Government employees at risk, the Government never would have paid Defendants.

II. PARTIES

The Relator and Government Plaintiff

11. Shawn Lawler, DDS is a dentist who worked at multiple American military bases and diplomatic facilities in Iraq under a State Department contract with his employer Comprehensive Health Services ("CHS"), a company headquartered in Cape Canaveral, Florida,

⁸ GovTribe, *Definitive Contract FA861514C6020* (last visited Apr. 24, 2019).

⁹A picture of the Austell Laboratories Tramadol package is attached as **Exhibit 2**.

within the Middle District of Florida. Dr. Lawler worked for CHS between April 2014 and September 2018. After leaving CHS between September 2018 and December 2018, he came back to work in the Middle East in late December 2018. Initially, he started working for CHS at the Balad base. Then Dr. Lawler was assigned to work full-time at the Baghdad Diplomatic Support Center adjacent to the Baghdad International Airport. After that, Dr. Lawler was assigned to the Basra consulate and then to the U.S. Embassy once a dental clinic was established there in January 2016.

12. Dr. Lawler acquired first-hand knowledge about the 2011 procurement process which resulted in a contract (SAQMMA 11-R-0010) with the U.S. Department of State to provide medical services in Iraq that were “in accordance with US or equivalent [European Union] medical standards on a 24 hour basis, 365 days of the year”¹⁰ and the 2014 Sallyport Global Services Ltd. contract, which subcontracted to CHS Middle East LLC to provide medical services at Balad Air Base (Contract No. FA861514C6020).¹¹ Dr. Lawler observed the initial and continued lack of compliance with the privacy and security requirements under the HIPAA Security Rule, Privacy Rule, and NIST 800-53, rev. 4, as well as lack of compliance with the pharmacy operations (i.e., no pharmacist present), dispensing of drugs by pharmacy techs and the purchase of controlled substances (i.e., tramadol hydrochloride) from non-United States or non-European Union manufacturers. Instead, Defendants opted to use Austell Laboratories (Pty) Ltd., 52 Mineral Crescent, Crown Ext. 3, Johannesburg, 2092, South Africa and charged the United States Government far in excess of what the Defendants’ cost was to procure the drugs illegally.

13. The United States is a Plaintiff for which recovery is sought for damages on

¹⁰ Pre-solicitation Materials are attached as **Exhibit 1**.

¹¹ GovTribe, *Definitive Contract FA861514C6020* (last visited Apr. 24, 2019).

behalf of the United States Department of State, the Department of Health and Human Services (“HHS”), the Department of Defense (“DOD”), and other relevant federal programs.

The Defendants

14. Caliburn International Corporation, which is headquartered at 10701 Parkridge Boulevard, Suite 200, Reston, Virginia 20191, was founded by DC Capital Partners to provide consulting, engineering, medical, and environmental services as well as large-scale program management in support of national defense, international diplomacy, and homeland security client readiness markets.¹² Caliburn consists of four subsidiary companies that were previously solely under the control of DC Capital:

- Sallyport, which was a subsidiary of Michael Baker, a DC Capital portfolio company that acquired Sallyport in 2011;
- Janus, which DC Capital acquired in December 2017;
- CHS (Comprehensive Health Services), which DC Capital acquired in March 2018; and
- PT&C, which DC Capital acquired in March 2018.

15. Comprehensive Health Services, LLC, (“CHSi”) was founded in 1975 and “is one of the nation’s largest and most experienced providers of medical management services.”¹³ CHS partners with “commercial companies, international customers, and the U.S. Government to solve the highly complex, large-scale health care challenges they face by implementing and managing cost-effective, customized medical programs for large and dispersed workforces.”¹⁴

¹² Caliburn, *About Caliburn International, LLC*, <https://www.caliburnintl.com/about-caliburn> (last visited Apr. 27, 2019).

¹³ CHS, *Why Choose Us*, <https://www.chsmedical.com/about> (last visited Apr. 27, 2019).

¹⁴ *Id.*

Comprehensive Health Services is the sole shareholder of Comprehensive Health Services International, Inc. (CHSI). CHSI in turn is the sole member of CHS Middle East, L.L.C., CHS Americas, L.L.C., and CHS World Services, L.L.C. CHS Middle East, L.L.C. was formed to carry out operations in the Middle East region.¹⁵ ¹⁶

16. CHS was a prime contractor with the State Department to provide medical services to American personnel in Iraq starting in 2011 and then became a subcontractor to the State Department under a company named Sallyport Global Services, Ltd. in 2014 to continue to provide these same services.¹⁷

17. Founded in 2008, CHS Middle East (“CHSme”) is a wholly owned subsidiary of Comprehensive Health Services, Inc. (CHSi).¹⁸ Its corporate address is listed as that of Caliburn. CHSme provides onsite health centers for the U.S. government and national examination programs for government and commercial clients. In April 2014, CHSme was selected by Sallyport Global Services Ltd as a subcontractor to provide medical services to American personnel in Iraq under a multi-year contract with the U.S. Government.¹⁹

¹⁵ Caliburn International Corporation, *SEC Form S-1*, p. F-100 (2018), <https://www.sec.gov/Archives/edgar/data/1750690/000119312518303218/d632104ds1.htm>.

¹⁶ Unless otherwise indicated, “CHS” refers to the parent company and subsidiary companies as identified herein, unless a specific entity is mentioned.

¹⁷ Comprehensive Health Services, *CHS Middle East wins second major medical services contract in Iraq* (Apr. 28, 2014), <https://www.chsmedical.com/newsroom/chs-middle-east-wins-second-major-medical-services-contract-iraq>.

¹⁸ Bloomberg, *CHS Middle East, LLC*, <https://www.bloomberg.com/profiles/companies/9246061Z:US-chs-middle-east-llc> (last visited Apr. 27, 2019).

¹⁹ Market Watch, *Sallyport Global Services Ltd., a Michael Baker International wholly owned subsidiary, selects CHS Middle East, LLC to provide critical medical services at Balad Air Base*,

18. Sallyport Global Services Ltd., is an international services company with its corporate headquarters located at 11921 Freedom Drive, Suite, 1000, Reston, VA 20190. In 2014, Sallyport selected CHSme as its subcontractor to provide medical services to both government and military personnel at Balad Air Base in Iraq.²⁰

III. JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over these claims brought under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, pursuant to 31 U.S.C. §§ 3730 and 3732. This Court has supplemental jurisdiction to entertain potential common law causes of action, such as unjust enrichment under 28 U.S.C. §§ 1345 and 1367(a).

20. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a) because that section of the False Claims Act authorizes nationwide service of process, and because the Defendants engage in interstate commerce through providing medical services to United States Government employees both in the United States and internationally, which emanate from Cape Canaveral, Florida.

21. Venue is proper in this district pursuant to 31 U.S.C. § 3732(a) and under 28 U.S.C. §§ 1391(b) and 1395(a), because the Defendants transact business in the Middle District of Florida.

22. There have been no public disclosures of the allegations and transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730.

23. Relator is unaware of any public disclosures. To the extent there has been such a public disclosure of any of Relator's allegations herein, he is an original source of those allegations

one of the largest military bases in Iraq (Apr. 28, 2014), <https://www.marketwatch.com/press-release/chs-middle-east-llc-wins-second-major-medical-services-contract-in-iraq-2014-04-28>.

²⁰ See <https://www.chsmedical.com/newsroom/chs-middle-east-wins-second-major-medical-services-contract-iraq> (Apr. 28, 2014).

within the meaning of 31 U.S.C. § 3730(e)(4)(B). Relator possesses direct and independent knowledge of the information on which the allegations are based. Relator also voluntarily disclosed to the Government this information prior to the filing of this complaint. *See* 31 U.S.C. § 3730(e)(4)(B).

24. Pursuant to 31 U.S.C. § 3730(b)(2), this action is being filed under seal, and has not been served on the Defendants. Relator has provided the United States Attorney General and the United States Attorney for the Middle District of Florida with a copy of the Complaint and a Disclosure Statement (separately submitted containing all material evidence in support of this Complaint).

IV. STATUTORY BACKGROUND

False Claims Act

25. Originally enacted in 1863 during the Civil War, the False Claims Act was substantially amended by the False Claims Amendments Act of 1986, signed into law on October 17, 1986; and by the Fraud Enforcement and Recovery Act of 2009, which was signed into law on May 20, 2009. Congress's intent was to enhance the Government's ability to recover losses sustained as a result of fraud against the United States and to provide a private cause of action for the protection of employees and others who act in furtherance of the purposes of the Act. Congress acted after finding that fraud in federal programs and procurement is pervasive and that the Act, which Congress characterized as the primary tool for combating fraud in government contracting, needed to be modernized.

26. The False Claims Act establishes civil penalties and treble damages liability to the United States for violations of the Act including, among other things: knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval; and knowingly

making, using, or causing to be made or used, a false record or statement material to a false claim. 31 U.S.C. § 3792(a)(1).

27. To show that an entity acted "knowingly" under the False Claims Act, it must be proven that the entity, with respect to information: (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. It is not necessary to prove that the entity had the specific intent to defraud the United States. 31 U.S.C. § 3729(b)(1).

28. Under the False Claims Act, the United States is entitled to recover three times the amount of each claim and, for each claim or overpayment, a civil penalty of not less than \$5,500 and not more than \$11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 for violations that occurred prior to November 2, 2015 and not less than \$11,181 and not more than \$22,363 for violations that occurred after November 2, 2015.

29. As the FCA's legislative history illustrates, "[c]laims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program."²¹ There are three broad categories of claims: (1) reverse false claims; (2) factually false claims; and (3) legally false claims. *Kane v. Healthfirst, Inc.*, 2015 WL 4619698 (S.D.N.Y. Aug. 3, 2015).

30. A reverse false claim occurs when any person knowingly and improperly avoids or decreases an "obligation" to pay the government in violation of 31 U.S.C. § 3729(a)(1)(G).

31. A factually false claim is defined as an "incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001).

²¹ S. REP. No. 345, 99th Cong., 2d Sess. 9 (1986), reprinted in 1986, U.S.C.A.A.N. 5266, 5274.

32. Legally false claims are predicated on an express or implied false certification of compliance with a regulation, statute or contract term. *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016) established that both express and implied legally false claims may form a valid basis for a False Claims Act case. When evaluating a legally false claim, the United States Supreme Court in *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989 (2016) required that a plaintiff/relator substantiate that compliance with the regulations was material to the government's decision to pay, and that the defendants had knowledge of the falsity of the claim. “[I]t can be reasonably inferred that in each situation where the government was overbilled, the overbilling would have been capable of influencing the government's payment decision.” *United States of America and State of Florida ex rel. Meria Broadnax v. Sand Lake Cancer Center, P.A.*, 2019 WL 423156, at *5 (M.D. Fla. Feb. 4, 2019) (upholding the relator's argument as quoted and denying Defendants Motion for Summary Judgment).

33. Compliance with a variety of laws and regulations is material to the government's decision to contract with persons and pay claims associated with services. “In general, a false statement is material if it has ‘a natural tendency to influence, or [is] capable of influencing, the decision of the decision-making body to which it was addressed.’” *Neder v. United States*, 527 U.S. 1, 16 (1999) (quoting *United States v. Gaudin*, 515 U.S. 506, 509 (1995); cited by *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016)).

Ownership and Control

34. Recently, the United States Department of Justice intervened in a similar case, *United States ex. rel Mdrano and Lopez v. Diabetic Care Rx, LLC dba Patient Care America, et al.*, Case No. 15-cv-62617 (S.D. Fla.). In Diabetic Care, Defendant RLH, through principals Michel Glouchevitch and Kenneth D. Hubbs, the Chairman of PCA's Board of Directors, Robert Funari,

because of their ownership and control, agreed to and ratified the practices of utilizing telemarketing, waiving patient co-payments without establishing the inability to pay and paying kickbacks, either directly or indirectly, in cash or in kind in order to increase revenues. Defendants conspired to defraud the United States Government. As set forth in its November 2018 U.S. Securities and Exchange Commission Filing, Caliburn maintains control over its subsidiary companies. The CHS Chief Financial Officer is now CEO of Caliburn. The former President of CHS is now COO of Caliburn. DC Capital Partners Founder Thomas Campbell serves as Chairman of the Caliburn board of directors.²²

Federal Acquisition Regulation

35. The Federal Acquisition Regulation, codified in 48 C.F.R. Parts 1-53, governs the acquisition of goods and services by executive branch agencies.²³ The purpose of “[t]he Federal Acquisition Regulations System is established for the codification and publication of uniform policies and procedures for acquisition by all executive agencies. The Federal Acquisition Regulations System consists of the Federal Acquisition Regulation (FAR), which is the primary document, and agency acquisition regulations that implement or supplement the FAR.”²⁴ There are four elements that comprise FAR’s performance standards: (1) [s]atisfy the customer in terms of cost, quality, and timeliness of the delivered product or service...; (2) [m]inimize administrative

²² G. Armstrong, *Wall Street Banks & Former Defense Officials Looking to Cash In on Child Detentions* (Feb. 13, 2019), <https://news.littlesis.org/2019/02/13/wall-street-banks-former-defense-officials-looking-to-cash-in-on-child-detentions/>.

²³ See <https://www.law.cornell.edu/cfr/text/48/chapter-1>.

²⁴ 48 C.F.R. § 1.101.

operating costs; (3) [c]onduct business with integrity, fairness, and openness; and (4) [f]ulfill public policy objectives.²⁵

36. FAR provides the foundation for procurement; however, FAR supplements, individual agency regulations and additional guidance documents may also apply.²⁶ Pursuant to 48 C.F.R. §2.101(b), “acquisition” means:

acquiring by contract with appropriated funds of supplies or services (including construction) by and for the use of the Federal Government through the purchase or lease, whether the supplies or services are already in existence or must be created, developed, demonstrated, and evaluated. Acquisition begins at the point when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and those technical and management functions directly related to the process of fulfilling agency needs by contract.

37. Government funds are involved because payment for the procured goods and/or services is paid out of the United States Treasury that are “charged to an appropriation provided by or derived from an act of Congress.”²⁷ IT related goods and services that are procured by Federal government agencies are ultimately paid for by the U.S. Treasury.

²⁵ 48 C.F.R. §1.102-2(a)-(d).

²⁶ Congressional Research Service, *The Federal Acquisition Regulation (FAR): Answers to Frequently Asked Questions* (2015), <https://fas.org/sgp/crs/misc/R42826.pdf>.

²⁷ Office of the General Counsel, U.S. Gov’t Accountability Office, *Principles of Federal Appropriations Law*, Vol. 1, at 2-4 to 2-5 (3d ed., 2004), at <http://www.gao.gov/assets/210/202437.pdf>.

Truth-in-Negotiations Act

38. Promulgated in the early 1960s, the Truth-in-Negotiations Act (“TINA”), Pub. L. 87-653 (Dec. 2, 1962) (codified by 10 USC 2306a) mandates that government contractors provide a full disclosure of the costs that are expected to be incurred during the performance of the contract. Failing to do so may result in civil (and potentially criminal) liability arising under the False Claims Act.

39. For example, CyTerra Corporation paid the United States Department of Justice \$1.9 million to “resolve civil liability arising from its failure to provide the U.S. Department of the Army with accurate, complete and current cost or pricing data for its sale of mine detectors, the Justice Department announced today. … Under the Truth in Negotiations Act, CyTerra was required to provide cost or pricing data that was ‘accurate, complete and current.’ The government alleged that if the Army had received such information, it would have negotiated a lower price.”²⁸ CyTerra artificially inflated its costs, which violated the Truth-in-Negotiations Act, and resulted in violations of the False Claims Act.

40. Another False Claims Act case that was premised on the Truth-in-Negotiations Act and resulted in \$98.5 million penalty occurred in 2006 when PeopleSoft, which was subsequently acquired by Oracle, made defective disclosures that were not current, accurate and complete concerning the sale of software licenses and related maintenance services between March 1997

²⁸ U.S. Department of Justice, *CyTerra Corporation Agrees to Pay \$1.9 Million to Resolve False Claims Act Allegations* (Jul. 2, 2013), <https://www.justice.gov/opa/pr/cyterra-corporation-agrees-pay-19-million-resolve-false-claims-act-allegations>. See also *United States ex rel. Bartczak, et al. v. CyTerra Corporation*, Civil Action No. 06-CA-10550-NMG.

and September 2005.²⁹ According to then Deputy Attorney General McNulty. “The program works well when vendors follow the disclosure rules and provide GSA with the information it needs to negotiate good prices for government purchasers. This agreement demonstrates the Department’s determination to hold vendors accountable for abusing GSA’s trust and damaging its programs.” At the time, this was the largest civil settlement obtained by the DOJ involving the GSA’s Multiple Award Schedule (“MAS”) program.

The Health Insurance Portability and Accountability Act of 1996 – HIPAA

41. Over two-decades ago, the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191 (Aug. 21, 1996) (“HIPAA”), was enacted, in part, to “combat waste, fraud, and abuse in health insurance.”

42. The Privacy Rule was subsequently promulgated and imposed standards to protect the privacy of individual’s protected health information. 65 Fed. Reg. 82461 (Dec. 28, 2000).

43. HIPAA guards patients’ PHI from disclosure outside of a limited group of people including treating health care professionals, without patients’ express permission. See 45 C.F.R. §§ 160.103, 164.502.

44. The Security Rule requires that certain technical, administrative and physical safeguards are implemented in order to ensure the confidentiality, availability and integrity of the PHI.

FISMA

45. “The Federal Information Security Management Act of 2002 (FISMA) and Federal Information Security Modernization Act of 2014 (also FISMA, which enhances and clarifies the

²⁹ U.S. Department of Justice, *Oracle Agrees to Pay \$98.5 Million for False Pricing Information Provided by PeopleSoft to Obtain Government Contract* (Oct. 10, 2006), https://www.justice.gov/archive/opa/pr/2006/October/06_odag_689.html.

original law) require US Government agencies to implement information security controls using a federal risk based approach to information security assessment.”³⁰ In turn, the individual agency is mandated to report annual compliance to the U.S. Office of Management and Budget (“OMB”). The primary framework for FISMA compliance is detailed in NIST Special Publication 800-53.

V. THE FRAUDULENT SCHEMES

A. Knowing and Intentional Submission of False Bids, Attestations, Certifications and Claims During the Procurement Process

46. The January 21, 2011 Pre-Solicitation Conference Power Point slides state explicitly that “medical records” were both an “additional requirement” of CHS’ contract and that such records “[m]ust be HIPAA compliant.” HIPAA’s rules apply to “Government programs” like this one “that pay for health care.....” **Exhibit 3.** Section 4.1903 of the Federal Acquisition Regulations requires that contracting officers “shall insert the clause at § 52.204-21, Basic Safeguarding of Covered Contractor Information Systems, in solicitations and contracts when the contractor or a subcontractor at any tier may have Federal contract information residing in or transiting through its information system.” 48 CFR § 52.204-21(b)(1)(i) requires contractors like CHS that store or transmit “federal contract information” to “limit information system access to authorized users”, as well as “processes acting on behalf of authorized users.”

47. Given the fact that HIPAA compliant medical records were an explicit requirement of this contract and that contractors like CHS were required by regulation to limit access to medical records to authorized users, systemic and widespread violations of HIPAA’s Security Rule was clearly material to the State Department’s decisions to pay CHS under this contract. Moreover, since HIPAA compliance was an explicit requirement of the contract, CHS also was required by

³⁰ *Id.*

45 CFR § 164.404 and § 164.410 to notify the State Department of any “breach of unsecured protected health information.”

48. According to its website, “Comprehensive Health Services takes compliance issues extremely seriously, assuring clients and partners that we comply with all government and industry standards. … Through the use of administrative, physical, and technical safeguards, paired with continuous training, we assure the confidentiality, integrity and availability of protected health information.”³¹ CHS also indicates that a Type II SOC 2 Audit was done by Kirkpatrick Price for the period of May 1, 2017 through November 30, 2017.³²

49. As Dr. Lawler witnessed first-hand during his deployment to Iraq to work at a CHS facility, there were materially inadequate technical, physical and administrative safeguards. There was never an auditor on site and there were major breaches of PHI and PII. When he mentioned this to CHS Chief Medical Officer Dr. Michael Wynn, Dr. Lawler was met with resistance. Subsequently, as detailed herein, Dr. Wynn indicated that he found major problems with cybersecurity and HIPAA compliance in relation to securing and protecting the confidentiality, integrity and availability of the data.

B. Knowing Failure to Secure Patients’ Protected Health Information and Knowing Failure to Disclose Known Breach

50. CHS knowingly maintained patient medical records, including but not limited to dental records, on its insecure P:drive computer system for many years, including the period prior to the last three years when Dr. Lawler was employed by CHS, thereby exposing this protected

³¹ CHS, *Compliance*, <https://www.chsmedical.com/compliance> (last visited Apr. 24, 2019).

³² CHS, *Comprehensive Health Services Completes SOC II Audit in November* (Dec. 4, 2017), <https://www.chsmedical.com/newsroom/comprehensive-health-services-completes-soc-ii-audit-november>.

health information to unauthorized persons, including Iraqi nationals employed at the facilities CHS served during the period the United States was fighting ISIS terrorists in Iraq.

51. In an email from CHS Chief Medical Officer Dr. Michael Wynn to the CHS dental staff on August 28, 2017, it was stated that Dr. Wynn had “discovered … a serious issue with the protection of patient privacy and compliance with HIPAA regulations” because “patient information is being stored on the P:Drive.” Dr. Wynn admitted that “[t]he P:Drive is not secured for patient information” and advised that “[i]t appears that this is a process that has been done for years”

52. In another email from Dr. Wynn to the CHS dental staff on August 30, 2017, Dr. Wynn stated that “[t]his incident had me look at all areas within the P:drive and I discovered multiple other stored PHI by other sections.” This demonstrates that CHS left more protected health information unsecured than merely dental records.

53. During a morning meeting on August 30, 2017, which Relator attended in person, Sonny Talbot, PA-C, who was leading the meeting, indicated that the P drive was not a secure drive, and that patient files being scanned to the P drive was a HIPAA violation. Talbot added that if the ACOR or COR [Contracting Officer Representative] found this violation CHS would lose its contract. Talbot went on to say that if the COR ever found out about this violation everyone would lose their jobs. To further emphasize this threat, Talbot added “We all want to keep our job, right?” John Duggar added that the HIPAA violation for each scan on the P Drive was \$25,000 per scan and that there were thousands on the drive. He also stated that the problem with the drive was that there was no way for them to track who went into a file and looked at it.

54. In an email from Deputy Program Manager Nelson Aguilar to “MSSI_OCONUS” on

September 1, 2017, Mr. Aguilar advised that “[a]s we move forward with the findings on the P:Drive we would like to remind everyone that we need to keep PII as confidential as possible.” Mr. Aguilar then directed all recipients of this email to complete an on-line HIPAA refresher training course.

55. Despite recognizing the need to fix CHS’s patient record system and to have all CHS employees retrained on their HIPAA obligations, CHS knowingly chose not to inform the State Department or the affected patients of the breach of their medical records as required by 45 CFR § 164.404 and § 164.410. Indeed, CHS management intimidated CHS employees to refrain from reporting this breach to the Government by threatening them with the loss of their jobs.

56. As observed by Dr. Lawler, Dr. Wynn very quickly realized that the P:Drive was not secure within hours of looking into this issue on August 28, 2017. The speed with which he was able to reach this conclusion must mean that some CHS employees were aware that the P:Drive was not secure.³³ This means that CHS as an organization had the requisite knowledge required under the False Claims Act. Alternatively, CHS was reckless in failing to understand that it was storing protected health information on an unsecure computer system on bases which employed Iraqi nationals at a time when ISIS fighters were attacking Americans in Iraq.

C. Knowingly Operating Pharmacies at Several Facilities without the Required Supervision of any Pharmacist

57. CHS and Sallyport’s contracts with the State Department required that CHS provide both pharmacy and pharmaceutical services. **Exhibit 1 at 00189.** In order to provide these services CHS employed pharmacy technicians at multiple bases. But pharmacy technicians must

³³ The Eleventh Circuit holds that “liability of a corporation for a False Claims Act violation may arise from the conduct of employees other than those with ‘substantial authority and broad responsibility.’” *Grand Union Co. v. United States*, 696 F.2d 888, 891 (11th Cir. 1983), quoting *United States v. Hanger One, Inc.*, 563 F.2d 1155, 1158 (5th Cir. 1977).

the direct supervision of licensed pharmacists. *See, e.g.*, Florida Statute § 465.014(1) (“All such delegated acts [of pharmacy technicians] must be performed under the direct supervision of a licensed pharmacist who is responsible for all such acts performed by persons under his or her supervision”). Relator Lawler knows from first-hand, on-site experience that no pharmacist was present at the U.S. Embassy or the Basra consulate and that a pharmacist was present at the Baghdad Diplomatic Support Center only for nine months of the year.³⁴

58. In an analogous case, the Government argued that defendants “falsely certified claims by failing to disclose that nurse practitioners in the pain management clinics were not supervised as required by law.” *United States v. Anderson*, 271 F.Supp.3d 950, 956 (M.D. Tenn. 2017). The Government “allege[d] that Anderson caused false claims to be submitted without disclosing that the nurse practitioners were not properly supervised.” *Id.*

59. Here, CHS and Sallyport agreed to provide and purported to provide pharmacy and pharmaceutical services as part of its State Department contract, but failed to disclose that its pharmacy technicians at the U.S. Embassy, the Basra consulate and, at times, at the Baghdad Diplomatic Support Center were not under the direct supervision of licensed pharmacists. Instead, pharmacy technicians were dispensing prescription medications unsupervised – often for weeks at a time. CHS fraudulently pretended that it had provided the required pharmaceutical services in accordance with FAR and the United States Food and Drug Administration (“FDA”), despite knowing that it had not.

D. Knowingly Importing Non-Approved Drugs, Including Controlled Substances into Iraq from South Africa

60. CHS’s contract with the State Department required that medical supplies had to be

³⁴ Pharmacists were required to work for 90 days in a row, followed by 30 days off. CHS did not supply a backup pharmacist during a pharmacist’s 30 day-off period.

FDA or European Medicines Agency (EMA) approved products only. This requirement ensured that CHS patients were treated with quality medicines. But, Dr. Lawler knows from personal experience that CHS imported versions of such controlled substances as tramadol, hydrocodone and oxycodone into Iraq from South Africa. These medications were neither FDA-approved nor EMA-approved and consequently were not permitted to be dispensed by CHS's or Sallyport's personnel under the State Department contract.³⁵

61. In addition, the State Department contract did not permit the use of controlled substances obtained from a third country, such as South Africa. For example, CHS routinely imported controlled substances such as Tramadol from Austell Laboratories, which is located in Johannesburg South Africa. **Exhibit 2.** The State Department's Response to Industry Questions and Comments, Request for Proposal Dated February 11, 2011, stated: "If the contractor wants to bring controlled substances from the US, he will have to register as a DEA exporter and will have to comply with the international treaties and laws of Iraq. The only other option is to enter an agreement with a local supplier in that part of the world." **Exhibit 4** at 8 of 39. Here, CHS neither imported controlled substances from the United States with DEA authorization nor obtained such medications from a local supplier. Consequently, CHS knowingly violated the State Department contract.

VI. CAUSES OF ACTION

COUNT I

PRESENTING AND CAUSING TO BE PRESENTED FALSE AND FRAUDULENT CLAIMS IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(A)

62. Relator realleges and incorporates by reference each allegation in each of the

³⁵ CHS paid \$0.25 or less per pill for South African Vicodin/hydrocodone equivalents, while charging the United States Government \$2.00 - \$4.00 for that same pill.

preceding paragraphs as if fully set forth herein.

63. From at least 2011 through the present, Defendants knowingly presented and caused to be presented claims to the United States Department of State for health care services provided to Government employees in Iraq which were false and fraudulent because Defendants falsely impliedly certified that such services had been provided in accordance with FAR, NIST and/or HIPAA standards, when in fact they had not; because Defendants falsely impliedly certified that pharmaceutical services had been provided by licensed pharmacists when in fact they had been provided by pharmacy technicians who were not acting under the direct supervision of licensed pharmacists; and because Defendants falsely impliedly certified that medications dispensed, including controlled substances, were FDA or European Medicines Agency approved products, but which instead had been imported into Iraq from South Africa.

COUNT II

REVERSE FALSE CLAIMS IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(G)

64. Relator realleges and incorporates by reference each allegation in each of the preceding paragraphs as if fully set forth herein.

65. From at least 2011 through the present, Defendants knowingly concealed and improperly avoided obligations to pay or transmit money to the Government, specifically refunds of known overpayments due to the United States Department of State for health care services which had not been provided to Government employees in Iraq in accordance with FAR, NIST and/or HIPAA standards; for pharmaceutical services which had not been provided by licensed pharmacists as required by contract and applicable law; and for medications dispensed which were not FDA or European Medicines Agency approved products as required by contract and applicable law.

66. Plaintiff seeks relief against Defendants under Section 3729(a)(1)(G) of the False Claims Act, for all false and fraudulent claims that Defendants caused to be presented.

67. Accordingly, as set forth above, Defendant knowingly caused to be made or used false records and/or statements to conceal, avoid, or decrease obligations to pay or transmit money or property to the United States. Thus, the United States has incurred losses to be determined at trial.

68. Pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1), Defendant is liable to the United States under the treble damage and civil penalty provisions for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each violation committed by Defendant on or before November 2, 2015, and not less than \$11,181.00 and not more than \$22,363.00 for each violation committed by Defendant after November 2, 2015, plus three (3) times the amount of damages which the United States has sustained because of Defendants' actions.

COUNT III

CONSPIRACY IN VIOLATION OF 31 U.S.C. § 3729(a)(1)(C)

69. Plaintiff repeats and realleges the allegations above as if fully set forth herein.

70. Plaintiff seeks relief against Defendants under Section 3729(a)(1)(C) of the False Claims Act, for all false and fraudulent claims that Defendants caused to be presented.

71. Through the acts and inaction alleged above, Defendants, acting together in concert as each other's contractors, agents, partners, and/or representatives in making, using or causing to be made or used, false records or statements material to an obligation to pay or transmit money to the United States, or in concealing, avoiding or decreasing an obligation to pay or transmit money to the United States, were acting within the course, scope and authority of such contract, agency, partnership and/or representation for the conduct described herein and conspired to engage in actions and inactions in violation of the False Claims Act.

72. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

73. Pursuant to the False Claims Act, 31 U.S.C. § 3729(a)(1), Defendant is liable to the United States under the treble damage and civil penalty provisions for a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each violation committed by Defendant on or before November 2, 2015, and not less than \$11,181.00 and not more than \$22,363.00 for each violation committed by Defendant after November 2, 2015, plus three (3) times the amount of damages which the United States has sustained because of Defendants' actions.

VII. DAMAGES

74. Relator repeats and re-alleges each allegation in each of the preceding paragraphs as if fully set forth herein.

75. The FCA imposes liability on any person who knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim; conspires to commit a violation of the False Claims Act or knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government. 31 U.S.C. § 3729(a).

76. Prior to 2016, the last increases to the penalties for False Claims Act violations occurred on August 30, 1999 and changed the minimum from \$5,000.00 to \$5,500.00 and the maximum from \$10,000.00 to \$11,000.00, plus treble damages. 64 Fed. Reg. 47099, 47104. On August 1, 2016, the U.S. Department of Justice published Interim Final Rules, which significantly increased penalties under the False Claims Act for the first time in nearly eighteen years. Now, for

violations occurring after November 2, 2015, the new minimum and maximum penalties are \$10,781.00 to \$21,563.00 plus treble damages. 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016).

77. Here, to the best of Relator's knowledge, the Defendants submitted false claims to the Government beginning in 2011.

VII. PRAYER FOR RELIEF

Wherefore, Relator respectfully requests this Court enter judgment against Defendants and order:

- A. That Defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq.*; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812;
- B. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than \$5,500.00 and not more than \$11,000.00 for each violation of 31 U.S.C. § 3729 prior to November 2, 2015;
- C. That this Court enter judgment against Defendants in an amount equal to treble (three times) the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than \$10,781.00 and not more than \$21,563.00 for each violation of 31 U.S.C. § 3729 after November 2, 2015, pursuant to 81 Fed. Reg. 42491, 42494 (Jun. 30, 2016);
- D. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;
- E. That Relator and his attorneys and the U.S. Government be awarded all costs of this action, including attorneys' fees and expenses; and
- F. For such other and further relief as this Court may deem proper.

IX. JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Relator demands a jury trial for all claims and issues so triable.

Dated: May 9, 2019.

Respectfully submitted,

/s/ Kevin J. Darken
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing False Claims Act Complaint has been furnished by hand delivery and certified mail return receipt requested to: United States Attorney Maria Chapa Lopez, United States Attorney's Office, 400 North Tampa Street, Ste 3200, Tampa, FL 33602; and to Attorney General William Barr, Dept. of Justice, 950 Pennsylvania Ave., N.W., Washington, D.C. 20530 on this 9th day of May, 2019.

Kevin J. Darken
Kevin J. Darken